DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

g3774d

DEC 13 2002

**WARNING LETTER**

**VIA FEDERAL EXPRESS**

Mr. Volker Bertram, President and CEO
VBM Medizintechnik GMBH
Robert-Bosch-Strasse 7
D-72172 Sulz a.N.
Germany

Dear Mr. Bertram:

On July 15-18, 2002, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your facility, which manufactures tracheostomy tubes, airway connectors and tubings for ventilators, and cufflator devices. These products are medical devices under the Federal Food, Drug, and Cosmetic Act (the Act), because they are intended for use in diagnosing or treating a medical condition or to affect the structure or a function of the body (Section 201(h) of the Act, 21 U.S.C. § 321(h)).

The inspection revealed that your medical devices are adulterated within the meaning of Section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current Good Manufacturing Practice (cGMP) requirements set forth in FDA's Quality System (QS) Regulation, codified in Title 21 of the Code of Federal Regulations, Part 820 (21 CFR Part 820). The inspector noted the following QS Regulation violations, which are also listed in the FDA Form 483 provided to your facility at the end of the inspection:

1. Failure, by management with executive responsibility, to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of Part 820 and your firm's established quality policy and objectives, as required by 21 CFR § 820.20(c). Specifically, your firm's procedure for management review lacks sufficient detail to ensure that your quality system complies with Part 820 and with your quality policy and objectives. Moreover, the procedure does not define the intervals at which management review will occur.

2. Failure to establish and maintain a design history file (DHF) containing or referencing records necessary to demonstrate that design reviews were conducted, as required by 21 CFR § 820.30(e). Our previous inspection

3. of your facility on March 2, 2000, also noted deficiencies in design control procedures.

4. Failure to validate the [redacted] used by [redacted] to manufacture airway connector parts for your firm with a high degree of assurance, as required by 21 CFR § 820.75(a).

5. Failure to document the justification for the manner in which you disposed of nonconforming product, as required by 21 CFR § 820.90(b)(1). For example, on March 11, 2002, your plant manager specially released out-of-specification Quicktrach Needles (30-04-004N/lot 0288/02) without documenting a justification. On March 14, 2002, your plant manager specially released out-of-specification housings for right angle swivel connector (60-60-555-5/control number 0313/02). Your plant manager also specially released out-of-specification single swivels (60-60-005-5/control number 0388102).

6. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA), as required by 21 CFR § 820.100(a)(1). Specifically, CAPA Procedure #14 did not include requirements for analyzing all appropriate sources of quality data to identify existing and potential causes of nonconforming product or other quality problems. Our inspection identified several sources of quality data that were not included in your CAPA procedures, including more than 200 complaints of medical device malfunctions.

7. Failure to establish and maintain CAPA procedures including requirements for investigating the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR § 820.100(a)(2). Specifically, an investigation was not made to determine the cause of cracks in the blister pack of the Quicktrach, a sterile product.

8. Failure to ensure that medical device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution, as required by 21 CFR § 820.130. Specifically, your firm had information indicating that the sealing temperature might adversely affect the blister pack material for the Quicktrach, a sterile product, but you failed to change your processes or containers to prevent the packaging from cracking or to prevent contamination of the product.

At a meeting with FDA representatives at the close of the inspection, you indicated that your firm planned to correct these violations by December 2002.

You have not provided documentation demonstrating that corrective actions have been implemented. Your response is, therefore, inadequate to resolve our concerns.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure compliance with each requirement of the Act and FDA implementing regulations. The specific violations noted in this letter and in the FDA Form 483 issued at the end of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by FDA. Particularly, if the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Please notify this office in writing within 15 days of receipt of this letter of the specific steps you have taken to correct the noted violations. In addition, please explain each step you are taking identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include in your response any documentation necessary to show your plans for correction. An English translation of any foreign language materials should also be included in your response. Your response should be sent to:

Christy Foreman, Chief
Orthopedic, Physical Medicine & Anesthesiology Devices Branch
Division of Enforcement B, Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850

If you fail to take prompt action to correct these deviations, FDA is entitled to initiate enforcement action without further informal notice to you. Under Section 801(a) of the Act, for example, FDA could refuse to admit your products into the United States, on the ground that they appear to be adulterated under Section 501(h). In addition, United States federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts.

If you have any questions, please contact Brenda Hayden at (301) 594-4659.

Sincerely yours,

Vladyslav Rocheys

for Philip J. Frappaolo
Acting Director
Office of Compliance
Center for Devices and
Radiological Health